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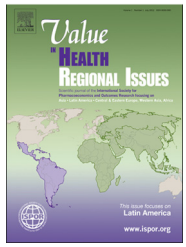

Patient-Reported Outcomes in Latin America: Implementation in Research and Role in Emerging HTA Systems

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ABSTRACT

Background: Patient-reported outcomes (PROs) are increasingly used to demonstrate the value of interventions and support health technology assessment (HTA). **Objective:** The objective of this work was to analyze trends regarding PROs in Latin America (LatAm), highlight challenges in the application of PROs in this region, and suggest solutions. **Methods:** A team of researchers with expertise in PROs conducted a nonsystematic PubMed literature search pertaining to the use of PROs in LatAm. The experts also drew on their experience working with PROs to assess the application of PROs in LatAm. **Results:** The literature search yielded more than 4000 publications, with an increasing publication rate in recent years. PROs are being used in LatAm in various study types: instrument validation, phase III international clinical trials, health service research. A large Inter-American Development Bank study demonstrates the growing importance of PROs in the region. The growth in local value sets for the EuroQol five-dimensional questionnaire in LatAm reflects the regional emergence of HTA systems. Operational challenges relate to ensuring the use of good-quality questionnaires that, at a minimum, have undergone appropriate cultural adaptation and ideally have established psychometric properties. **Conclusions:** PROs are increasingly important in LatAm. Future efforts should aim to strengthen the operational and research infrastructure around PROs in the region. Innovation should be encouraged, including studying alternative methods of eliciting health utilities for economic evaluation. A wider scope around PRO uses for decision making by HTA bodies is an international trend with potential positive prospects in LatAm.

Keywords: Clinical trials as topic, drug industry, Latin America, multicenter studies as topic, outcome assessment (health care), Patients, Quality of Life, Questionnaires, self-report.

Introduction

Patient-reported outcomes (PROs) provide important insight into the patient experience with a disease or treatment that may facilitate health care decision making by prescribers and payers, as well as patients. Such data are collected directly from the patient, without interpretation from others [1], through the use of patient-reported outcome measures (PROMs), also referred to as instruments, questionnaires, or scales. In recent years, the competitive global marketplace has increasingly acknowledged the usefulness of PRO data to support labeling, communication strategies, and value messages.

PRO data may also demonstrate value for the purposes of health technology assessment (HTA). HTA provides quantitative estimates of the efficacy and safety of new drug entities as well as insight into the cost-effectiveness of therapies. Such data are used to guide reimbursement and market access decisions. There is growing recognition that when balancing costs and effectiveness, it is important to include inputs reflecting the patients' voice. As such, the patient's voice, as evaluated by PROMs in pharmaceutical interventional studies, is increasingly taken into consideration in HTA evaluations in both the European Union and the United States [2].

In Latin America (LatAm), HTA systems are emerging and consolidating. Currently, there are three main agencies that oversee HTA at a national level, along with a number of other private and public agencies. Given constrained health care budgets, countries increasingly require a formal evaluation of new health care technology to assess value for money. Therefore, regulatory approval of a new product must be accompanied by data that will demonstrate the value of the product in order to secure reimbursement [3].

Integrating PROMs into clinical research and seeing that the resulting data are used appropriately in the health care decision-making process is not without challenges. There are various challenges in the integration of PROMs in multiregional trials, with some concerns specific to LatAm such as cultural impact/literacy level and technology infrastructure [4]. In regard to

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economic evaluation, population-specific health utility values may not be readily available for use in cost-effectiveness evaluation. Also, the value of PRO data may not be recognized for individual and population decision making.

The intent of this article was to assess the progress of integrating PROs into clinical research and decision making in LatAm, identify the challenges that may currently inhibit the integration of PROs in these practices, and propose potential solutions.

Methods

Three pharmaceutical representatives with expertise in PRO development and implementation in clinical studies, one PRO expert, and one LatAm researcher with expertise in health-related quality of life reviewed the PRO research and applications landscape in LatAm clinical trials and health services research. An effort was made to identify issues that are applicable across therapeutic areas. The relevant literature was identified through a PubMed literature search using the names of LatAm countries as MeSH terms, or in title/abstract, and combining those terms with the MeSH term "quality of life" or "quality of life" in title/abstract (Table 1). The search included all articles from 1974 through October 25, 2013; however, few studies were identified before 1990. No attempt was made to perform a systematic review of this literature. Instead, the present review was used to complement the expertise and qualitative discussion of the authors along with feedback gathered at a recent seminar at which the authors engaged health care decision makers from different LatAm countries.

Results

Research and Operational Landscape for PROs in Latin America

Research landscape

The initial search (search no. 1) of PubMed identified 4000 publications using the term "quality of life" in the title, abstract, or MeSH term, combined with relevant terms for LatAm countries (Table 1 and Fig. 1). When limiting the search to only the title or the MeSH term, 2500 articles were found (Table 1, search no. 2). When reviewing the results by date of publication, it was found that the number of publications per year has steadily increased

Table 1 – PubMed search terms and results (October 25, 2013).

Search/date	Search terms	Number of PubMed hits (1974–October 25, 2013)
No. 1 "quality of life" in title, abstract, or MeSH term	(("argentina"[MeSH Terms] OR "argentina"[All Fields]) OR ("brazil"[MeSH Terms] OR "brazil"[All Fields]) OR ("mexico"[MeSH Terms] OR "mexico"[All Fields]) OR ("chile"[MeSH Terms] OR "chile"[All Fields]) OR ("venezuela"[MeSH Terms] OR "venezuela"[All Fields]) OR ("peru"[MeSH Terms] OR "peru"[All Fields]) OR ("colombia"[MeSH Terms] OR "colombia"[All Fields]) OR ("bolivia"[MeSH Terms] OR "bolivia"[All Fields]) OR ("ecuador"[MeSH Terms] OR "ecuador"[All Fields]) OR ("uruguay"[MeSH Terms] OR "uruguay"[All Fields]) OR ("costa rica"[MeSH Terms] OR ("costa"[All Fields] AND "rica"[All Fields]) OR "costa rica"[All Fields]) OR ("guatemala"[MeSH Terms] OR "guatemala"[All Fields]) OR ("panama"[MeSH Terms] OR "panama"[All Fields])) AND ("quality+of+life"[tiab] OR "quality of life"[MeSH Terms])	4332
No. 2 "quality of life" in title or MeSH term	(("argentina"[MeSH Terms] OR "argentina"[All Fields]) OR ("brazil"[MeSH Terms] OR "brazil"[All Fields]) OR ("mexico"[MeSH Terms] OR "mexico"[All Fields]) OR ("chile"[MeSH Terms] OR "chile"[All Fields]) OR ("venezuela"[MeSH Terms] OR "venezuela"[All Fields]) OR ("peru"[MeSH Terms] OR "peru"[All Fields]) OR ("colombia"[MeSH Terms] OR "colombia"[All Fields]) OR ("bolivia"[MeSH Terms] OR "bolivia"[All Fields]) OR ("ecuador"[MeSH Terms] OR "ecuador"[All Fields]) OR ("uruguay"[MeSH Terms] OR "uruguay"[All Fields]) OR ("costa rica"[MeSH Terms] OR ("costa"[All Fields] AND "rica"[All Fields]) OR "costa rica"[All Fields]) OR ("guatemala"[MeSH Terms] OR "guatemala"[All Fields]) OR ("panama"[MeSH Terms] OR "panama"[All Fields])) AND ("quality+of+life"[ti] OR "quality of life"[MeSH Terms])	2554
No. 3— Validation studies	(("argentina"[MeSH Terms] OR "argentina"[All Fields]) OR ("brazil"[MeSH Terms] OR "brazil"[All Fields]) OR ("mexico"[MeSH Terms] OR "mexico"[All Fields]) OR ("chile"[MeSH Terms] OR "chile"[All Fields]) OR ("venezuela"[MeSH Terms] OR "venezuela"[All Fields]) OR ("peru"[MeSH Terms] OR "peru"[All Fields]) OR ("colombia"[MeSH Terms] OR "colombia"[All Fields]) OR ("bolivia"[MeSH Terms] OR "bolivia"[All Fields]) OR ("ecuador"[MeSH Terms] OR "ecuador"[All Fields]) OR ("uruguay"[MeSH Terms] OR "Uruguay"[All Fields]) OR ("costa rica"[MeSH Terms] OR ("costa"[All Fields] AND "rica"[All Fields]) OR "costa rica"[All Fields]) OR ("guatemala"[MeSH Terms] OR "guatemala"[All Fields]) OR ("panama"[MeSH Terms] OR "panama"[All Fields])) AND ("quality+of+life"[tiab] OR "quality of life"[MeSH Terms]) AND "Validation Studies" [Publication Type]	211

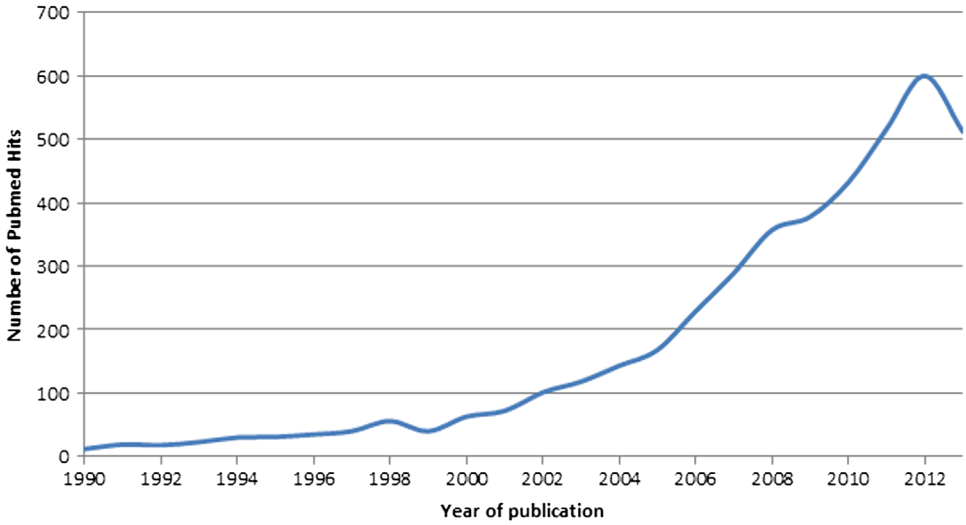

Fig. 1 – Number of PubMed hits (search no. 1).* *The search covered all results from 1974 through October 25, 2013; however, few studies were identified before 1990.

since the early 2000s, showing a clear increase in interest in this area of research.

The research on PROs in LatAm was grouped into the following five categories:

1. PROM content and psychometric validation studies: Validation of PROMs is an active area of development in LatAm where many PROMs are being developed or translated and culturally validated for use in the LatAm population.
2. Clinical research: PROs are currently included as part of large phase III multinational studies assessing pharmaceutical products. These studies are generally published in international journals with aggregated results, and the results for LatAm study participants are not directly captured in bibliographic searches as stand-alone publications.
3. PROs in regional or local research, including clinical trials and other prospective studies (international, regional, or local): For example, PROGIS [5] was a prospective observational study that investigated the evolution of gastrointestinal PROs in kidney transplant recipients. A battery of PROMs related to gastrointestinal health (Gastrointestinal Symptom Rating Scale), Gastrointestinal Quality of Life Index) and the Psychological General Well-being index were measured at baseline and 4 to 6 weeks. Sites from Argentina and Chile participated in the study.
4. PROs in other health services research studies: Cross-sectional studies in different groups, for example, health-related quality of life in primary care settings [6], in patients with multiple sclerosis [7,8], explanatory models for patient PROs [9], caregiver PROs [10], and PROs in prospective cohort studies [11].
5. PROs in population-based studies: At the population level, generic PROMs, such as the EuroQol five-dimensional questionnaire (EQ-5D), are frequently used to monitor or establish reference values for self-perceived health, complementing the traditional morbidity and mortality indicators. The EQ-5D was used in the 2003 Argentinean National Survey on Risk Factors [12] (the short- form 36 health survey was also used) and in a 2007 survey of 19 LatAm countries sponsored by the Inter-American Development Bank [13]. Use of the EQ-5D was used in the 2014 Chilean National Quality of Life Survey.

Operational landscape

Two unique aspects of PROMs are that they cannot be queried or corrected retrospectively and must be completed in a patient's native language or the language in which they converse on a day-to-day basis [2,4]. PRO data must be collected in a standardized manner so that the data are internally consistent and coherent for the purpose of analysis. A well-designed PROM will minimize bias, whereas a poorly designed PROM results in poor data quality that cannot be compensated for later in clinical trials.

As shown in the previous section, PROs are used in LatAm in diverse situations. The next section focuses on general recommendations to take into account when deploying studies containing PROMs.

Planning

Several elements are of critical importance in planning for the implementation of PROs, especially translated PROMs, within a clinical trial:

1. Which PROMs are to be included?
2. Is the context of use appropriate?
3. Where are the investigational sites located?
4. Will the patient complete the PROMs on paper or using an electronic device?
5. Do appropriately translated version(s) of PROM(s) exist or must they be newly created?
6. If translated versions exist, do they meet current regulatory standards?
7. When will translations be needed for ethics review?

Each of the items listed above should be established as early in the implementation process as is feasible to ensure the timely inclusion of PROMs in the trial.

Creating Validated Translations

The 2009 Food and Drug Administration Guidance on Patient-Reported Outcomes states that the sponsor should be prepared to demonstrate that sufficient care was taken to ensure that translated PROMs are conceptually equivalent to the original version [1]. Specifically, the agency intends to review the following:

1. The process used to translate and culturally adapt the PROM for populations that will use them in the trial;
2. The description of patient testing, language- or culture-specific concerns, and rationale for decisions made to create new versions;
3. Copies of translated or adapted versions; and
4. Evidence that content validity and other measurement properties are comparable between the original and new [translated] measures.

To meet these guidelines, sponsors are advised to develop new translations according to the ISPOR Good Translation Practices [14]. The reiterative translation and patient testing process is shown in Fig. 2. Evidence that this linguistic validation process was used to create new translations, including full harmonization and cognitive debriefing of the translation, can be used to support the assertion that the content validity and other measurement properties of the translations are comparable to those of the original PROM. A report describing the harmonization and pilot-testing phases of the translation development as well as certifications detailing the methodology used to create the translated version(s) should accompany all translations. Any translation lacking such detailed documentation risks being rejected by regulatory authorities.

Allowing Sufficient Time to Create the New Translations Is Essential

Because PROMs are most often developed in English, authors should assess the translatability of the new questionnaire and whether the concepts included are appropriate to a range of cultures. Typical areas that should be scrutinized include the following:

1. References to country- or religion-specific holidays such as Halloween and Christmas;
2. References to sports and leisure activities such as baseball, golf, and football;
3. The use of AM/PM instead of a 24-hour clock;
4. References to health care resources;
5. Idiomatic expressions;
6. Measurements of distance (English vs metric); and
7. Topics that may be culturally sensitive (e.g., erectile dysfunction and use of birth control techniques).

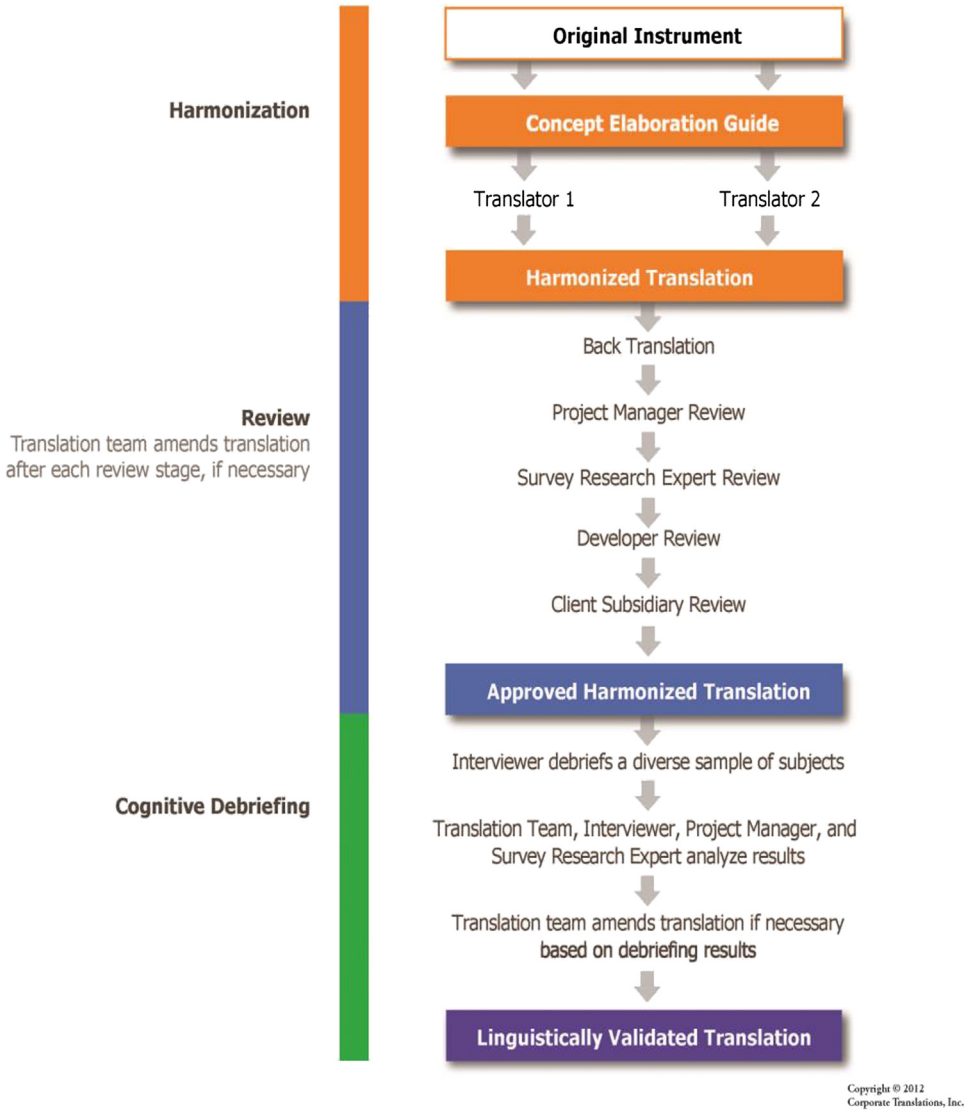

Fig. 2 – Linguistic validation process.

In most instances, during the translation process these items will require cultural adaptation or even need to be excluded from the measure entirely. Such cultural adaptation and psychometric validation are active areas of research in LatAm, as shown by the amount of work published and also intramural activities of sponsors preparing PROMs for use in multinational clinical trials that include LatAm countries.

Methods of Administration

Most of the validated PROMs were initially designed for paper administration. As the industry moves increasingly toward electronic administration of PROs (ePRO), several problems may result from failure to plan for ePRO administration early in the study implementation process. For example:

1. Learning that existing translations are worded for paper and not for ePRO or Interactive Voice Response System administration;
2. Selecting an inappropriate ePRO tool for administering the PROM (e.g., one in which the translation may be too long to fit on the device screens); and
3. Discovering that the local infrastructure cannot support the device.

In LatAm, PROMs are most commonly administered via paper. The increasing presence of health information technologies and mobile devices, however, can facilitate the conduct of studies on electronic platforms, which have been shown to increase data quality. Use of ePRO should be explored both in countries with more modern communication infrastructures and, when possible, in countries that are still developing such technology.

Other Concerns Specific to LatAm

1. Language: Although Spanish is the primary language spoken in LatAm, there are other countries where Portuguese or French is the dominant language. It is also important to consider the variety of dialects in each country. Although PROMs should be appropriately translated and validated for use in the specific target population, in some studies, in the absence of version(s) appropriate for the country, PROMs are implemented by using the closest language-equivalent version. For example, the Work Productivity and Activity Impairment Questionnaire for Asthma exists in Spanish for Chile. No version, however, is currently available for Argentina. If an Argentinian version is needed for a clinical trial being run in that country, one solution would be to pilot test the Chilean version in Argentina [14]. Other approaches may exist and should be discussed with a linguistic validation specialist. Overall, the practice of using a PROM developed for a specific target country in a country where it has not been pilot tested should be avoided or minimized because its use may compromise the concept validity of the translated PROM and result in problems in pooling data.
2. Literacy: Literacy levels vary greatly throughout LatAm, especially between urban and rural settings. Before implementing a study, the literacy level of the target population should be carefully assessed. It should be noted that even in regions with high literacy, such as urban areas, some groups may have difficulty understanding and answering PROMs (e.g., rural migrant communities), especially in studies that approach patients during usual care. In these cases, the likelihood of success may be addressed through including a pilot study and success will be largely dependent on appropriate study coordinator training.
3. Cultural taboo: Varying attitudes among cultures toward conditions with a particular social stigma, such as obesity or AIDS, may affect PRO data. For example, fear of stigma and discrimination associated with HIV in parts of the world prevent patients from reporting symptoms and seeking treatment. Also, reporting of taboo subjects such as income and sexual behaviors may be problematic in some societies.
4. Ethics review: Large phase III studies that include PROs are being conducted in LatAm. Although the ethics review covering these studies seems to appropriately address the risk-benefit of such questionnaires, the use of PROMs in observational studies can sometimes be challenged. Some ethics committees may have the perception that including PROMs makes a study interventional, and lack of experience of the less specialized centers can make these reviews more cumbersome than needed. More education and engagement is needed to address the gaps in understanding regarding the use of PROMs in observational research.

PROs and Health care Decision Making in Latin America

HTA in Latin America

Health technology assessment (HTA) is important across different health systems due to its potential to promote the rational use of health interventions, contribute to the allocation of scarce health care resources, and inform the impact of additional investments in health through health expenditures.

In LatAm, HTA systems first emerged in México in the 1980s and have steadily grown in prominence, especially over the last decade, with many being recognized as part of the International Network of Agencies for Health Technology Assessment (INAHTA). A summary of the key HTA institutions and trends in LatAM is provided below:

1. Argentina: The Instituto de Eficacia Clinica y Sanitaria [15], a nongovernmental HTA institute, was established in 2001. It is part of INAHTA [16] and plays an advisory role in the creation and consolidation of other HTA institutions in the region. HTA regulations appeared in the Superintendencia de Servicios de Salud, the government body in charge of creating and updating the social security compulsory coverage package. These regulations, however, were not fully implemented, and the country did not advance toward an established HTA system. In 2009, the National Health Technology Assessment Coordinating Unit was created in the Ministry of Health. This is the HTA National Coordinating Unit that is also part of INAHTA.
2. Brazil: The Department of Science and Technology of the Ministry of Health incorporated HTA into its remit in the year 2000 (Department of Science and Technology is a member of INAHTA). The National Commission for the Incorporation of Technology was established in 2011 and formally requires economic evaluation and budget impact models to assess pharmaceutical products. Brazil also introduced Rede Brasileira de Avaliação de Tecnologias em Saúde [17] in 2009, a resource to produce and disseminate HTA studies and enhance health care decision making.
3. Chile: The Unit for Health Technology Assessment [18] was established in 1997 as the HTA unit in the Ministry of Health of Chile and was the first LatAm institution to be recognized as part of INAHTA. Guidelines for Economic Evaluation were issued in 2012, and it is expected that HTA will gain prominence in Chilean health care decision making in the short or mid-term.
4. Colombia: After several failed attempts to reform the system, the Instituto de Evaluation de Tecnolgias Sanitaria [19] was created in 2011 and launched in 2012 as a national health technology agency to advice on the formulation and update of the health benefits package.

5. Mexico: In 2003, the Mexican National Health Council (Consejo de Salubridad General) [20] issued a regulation that required economic evaluation to assess the incorporation of products into the National Formulary. A government agency (Centro Nacional de Excelencia Tecnolgica en Salud) [21] was created in 2004, which is part of INAHTA and has a more active role in assessing medical technology. Around the same time, in response to a regulation by the National Health Council, companies began submitting economic evaluations, a trend that has steadily increased in recent years. In 2008, Guidelines for Economic Evaluation were issued, with a subsequent update in 2011. These are the first guidelines acknowledging an explicit threshold for cost-effectiveness.
6. Other initiatives: Worth noting are initiatives to strengthen the regional HTA network. An Andean Network of HTA was established in 2006 [22]. In 2010, redETSA, a regional network of HTA institutions, was proposed and launched via a Pan American Health Organization–led initiative. In 2012, the LatAM HTA community achieved a historic landmark when all state members signed a Pan American Health Organization resolution endorsing HTA in the region.

HTA and PROs

PROs have two main roles in HTA. In the current climate, the main focus is on health utilities that provide information for the valuation of health interventions in economic evaluations. PROs can also enter the decision-making process directly, as documentation of the burden of disease or value of an intervention.

Governments and other organizations that finance health care interventions are making increasing use of economic evaluation as a tool to support prioritization of health care expenditure. In general, cost-effectiveness and cost-utility interventions are favored over cost-benefit analyses. To perform a cost-utility analysis using differential quality-adjusted life-years, health valuations for all the health states in the study are needed on a scale of 0 to 1 (0 = death, 1 = full health). There are several options for the valuation of health states including direct elicitation (with time trade-off or visual analogue scale), use of generic utility measures such as the EQ-5D, or mapping from generic or disease-specific health-related quality-of-life measures.

The EQ-5D, a PROM, is one of the most prominent and widely used measures for the generation of health utility values. There are several value sets available for all the health states generated by the EQ-5D, and these values can be applied directly to health status when measured as EQ-5D profiles. In LatAm, there are currently three countries with local EQ-5D value sets: Argentina [23], Brazil [24], and Chile [25]. A "universal" set is also available, from work that derived the health state valuation for Hispanics living in the United States [26].

PROs could also have a role in individual decision making. For example, PROs are mentioned in a clinical guideline for the treatment of posttraumatic urethra stenosis in males, issued by the Instituto Mexicano de Seguridad Social [27], the biggest insurer in México. This guideline recommends use of the autocontrol of urine flow scale, a PRO, together with clinical exploration "under clinical suspicion" of a case [28]. This PRO is also recommended to guide clinical decisions.

Discussion

PROs are essential for demonstrating unmet medical need and the value of interventions in health care. PROs are increasingly used in different regions of the world, and LatAm is no exception to these trends. The high number of publications currently in the public domain that focus on LatAm and include quality of life in the title or abstract is evidence of this trend. It is worth noting that in the absence of the MeSH term "Patient Reported Outcomes," the MeSH term "quality of life" was used (as a MeSH term and for title/abstract). Thus, this search likely underreports the level of PRO research that exists in this field.

PROs are in use in various study contexts throughout LatAm, including large phase III international studies, observational research, PROM validation, and population surveys. It is important to continue to monitor these trends, and a systematic review of the literature of PROs in LatAm is recommended. Studies about comparative health status, like the one developed by the Inter-American Development Bank, should be encouraged, as well as population surveys taking advantage of PROs. It is also important to continue to increase the research capacity in the field; a mapping of experts and available trainings would be beneficial. Innovative designs should also be put forward. For example, in the PROGIS study, data were used to psychometrically validate the PROMs for Argentina and Chile [29]. This project added to the existing validation literature and also provided information on the test-retest reliability of the questionnaires, which had not been previously explored.

Having a suitable, culturally adapted, and psychometrically validated PROM is the ideal situation. Investigators working in hospitals and other health care environments have an important role in promoting this best research practice. Investigators should also have a central role in the development of any new PROM that will be deployed internationally. Such investigators should be mindful of key operational considerations, such as the need to ensure that PROMs used in LatAm trials have undergone sound cultural adaptation and translation. In addition, psychometric properties of questionnaires in LatAm settings, especially in diverse disease groups, need to be further explored and documented. Locally developed PROs may also be a reality; however, these should be applied only after appropriate consideration has been given to existing PROMs and the need for a novel measure has been fully established. It is also necessary to ensure consistent administration of PROMs and full understanding by patients as to the purpose of and their part in the study. This can be especially challenging in environments with high illiteracy or functional illiteracy, or even in urban environments in which literacy is high but the population is generally unable to comprehend the aim of the questionnaire or study.

Sponsors should be mindful of the issues involved in procuring or developing appropriately validated translations for inclusion in a clinical trial. Successful execution requires both planning and research. It is important to establish the methods by which new or existing translations are produced and to ensure that they are culturally appropriate for the target population. In addition, determining the mode of administration before initiating the translations can save precious time and reduce costs. With the growth of the telecommunication infrastructure worldwide, opportunities are emerging to conduct studies using electronic platforms such as cell phones or other mobile devices. PROMs, however, must be fully validated for use on these platforms before being deployed in a study [30]. Study teams must be mindful of these issues and employ study personnel with the skills to collect evaluable quality PRO data. All study methods should be fully validated by experts in the field before full implementation.

PROs appear to have a key role in the HTA processes; however, the extent to which PROs are used outside of cost-utility analysis is unclear. HTA trends are increasingly present in LatAm, with three countries now using HTA explicitly to make coverage decisions in their public subsystem (Brazil, Colombia, and México). Health utility measures, a subset of PROs, are a key component of the HTA process and are used to calculate quality-adjusted life-years, the metric value of interventions in

cost-utility economic analyses. Although a number of options are available to generate health utilities, emphasis has been placed on the use of the EQ-5D, a measure that has subsequently become one of the most widely used PROs worldwide. EQ-5D health valuation sets are available for Argentina, Chile, and Brazil, and there is also a universal set that is based on Hispanics living in the United States. It is expected that new value sets will be developed and countries such as Colombia and México are likely to lead this trend given the presence of a formal HTA system. Guidelines for economic evaluation in LatAM should also broadly reflect different options to health utility valuation. Research should be encouraged into alternative sources of health utility data collection, and HTA agencies should engage in a multistakeholder dialogue about the value of PROs in this process. This dialogue should expand beyond health utility generation, as HTA agencies worldwide are advancing toward a more comprehensive use of PROs in the health technologies assessment and appraisal process. To fully understand the value of PRO evidence in the HTA process, future studies should initiate a systematic review of the HTA literature and qualitative discussion with HTA stakeholders.

Conclusions

In this article, an overview of PROs and their application in LatAm together with challenges and a suggested agenda moving forward were presented. There is value in using PROs to explore the outcomes of health interventions, and also to enrich population and individual decision making in LatAm. Additional efforts should concentrate on a systematic review of the apparently vast PRO literature in LatAm, as well as highlighting additional opportunities and challenges, including ethics committees evaluation of PRO use in observational research as well as regulatory approaches to PROs in LatAm.

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